MEDICATION GUIDE

JENTADUETO (JEN ta doo e' toe) (linagliptin and metformin hydrochloride) Tablets

Read this Medication Guide carefully before you start taking JENTADUETO and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment. If you have any questions about JENTADUETO, ask your doctor or pharmacist.

What is the most important information I should know about JENTADUETO? Serious side effects can happen in people taking JENTADUETO, including:

1. Lactic Acidosis. Metformin, one of the medicines in JENTADUETO, can cause a rare but serious condition called lactic acidosis (a build-up of lactic acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in the hospital.

Stop taking JENTADUETO and call your doctor right away if you get any of the following symptoms of lactic acidosis:

- feel very weak or tired
- have unusual (not normal) muscle pain
- have trouble breathing
- have unusual sleepiness or sleep longer than usual
- have sudden stomach or intestinal problems with nausea and vomiting or diarrhea
- feel cold, especially in your arms and legs
- feel dizzy or lightheaded
- have a slow or irregular heartbeat

You have a higher chance of getting lactic acidosis if you:

- have kidney problems. People whose kidneys are not working properly should not take JENTADUETO.
- have liver problems
- have congestive heart failure that requires treatment with medicines
- drink alcohol very often, or drink a lot of alcohol in short-term ("binge" drinking)
- get dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot with activity or exercise and do not drink enough fluids.
- have certain x-ray tests with dyes or contrast agents that are injected into your body
- have surgery
- have a heart attack, severe infection, or stroke
- are 80 years of age or older and have not had your kidneys tested
- 2. Inflammation of the pancreas (pancreatitis) which may be severe and lead to death.

Certain medical problems make you more likely to get pancreatitis.

Before you start taking JENTADUETO:

Tell your doctor if you have ever had:

- inflammation of your pancreas (pancreatitis)
- stones in your gallbladder (gallstones)
- · a history of alcoholism
- high blood triglyceride levels

Stop taking JENTADUETO and call your doctor right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

What is JENTADUETO?

- JENTADUETO is a prescription medicine that contains 2 diabetes medicines, linagliptin and metformin. JENTADUETO can be used along with diet and exercise to lower blood sugar in adults with type 2 diabetes when treatment with both linagliptin and metformin is appropriate.
- JENTADUETO is not for people with type 1 diabetes.
- JENTADUETO is not for people with diabetic ketoacidosis (increased ketones in the blood or urine).
- If you have had pancreatitis in the past, it is not known if you have a higher chance of getting pancreatitis while you take JENTADUETO.
- It is not known if JENTADUETO is safe and effective in children under 18 years of age.

Who should not take JENTADUETO?

Do not take JENTADUETO if you:

- have kidney problems
- have a condition called metabolic acidosis or diabetic ketoacidosis (increased ketones in the blood or urine).
- are allergic to linagliptin, metformin, or any of the ingredients in JENTADUETO. See the end of this Medication Guide for a complete list of ingredients in JENTADUETO.

Symptoms of a serious allergic reaction to JENTADUETO may include:

- skin rash, itching, flaking or peeling
- raised red patches on your skin (hives)
- swelling of your face, lips, tongue and throat that may cause difficulty in breathing or swallowing
- difficulty with swallowing or breathing

If you have any of these symptoms, stop taking JENTADUETO and contact your doctor or go to the nearest hospital emergency room right away.

What should I tell my doctor before using JENTADUETO?

Before you take JENTADUETO, tell your doctor if you:

- have or have had inflammation of your pancreas (pancreatitis).
- have kidney problems

- have liver problems
- have heart problems, including congestive heart failure
- drink alcohol very often, or drink a lot of alcohol in short term "binge" drinking
- are 80 years of age or older, you should not take JENTADUETO unless your kidneys have been checked and they are normal
- are going to get an injection of dye or contrast agents for an x-ray procedure.
 JENTADUETO will need to be stopped for a short time. Talk to your doctor about when
 you should stop JENTADUETO and when you should start JENTADUETO again. See
 "What is the most important information I should know about JENTADUETO?"
- have type 1 diabetes. JENTADUETO should not be used to treat people with type 1 diabetes.
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if JENTADUETO will harm your unborn baby. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if JENTADUETO passes into your breast milk. Talk with your doctor about the best way to feed your baby if you take JENTADUETO.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. JENTADUETO may affect the way other medicines work, and other medicines may affect how JENTADUETO works.

Especially tell your doctor if you take:

- other medicines that can lower your blood sugar
- rifampin* (Rifadin[®], Rimactane[®], Rifater[®], Rifamate[®]), an antibiotic that is used to treat tuberculosis

Ask your doctor or pharmacist for a list of these medicines if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take JENTADUETO?

- Take JENTADUETO exactly as your doctor tells you to take it.
- Take JENTADUETO 2 times each day with meals. Taking JENTADUETO with meals may lower your chance of having an upset stomach.
- If you miss a dose, take it with food as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take 2 doses of JENTADUETO at the same time.
- If you take too much JENTADUETO, call your doctor or Poison Control Center at 1-800-222-1222 or go to the nearest hospital emergency room right away.
- Your doctor may tell you to take JENTADUETO along with other diabetes medicines.
 Low blood sugar can happen more often when JENTADUETO is taken with certain other diabetes medicines. See "What are the possible side effects of JENTADUETO?"

- You may need to stop taking JENTADUETO for a short time. Call your doctor for instructions if you:
 - o are dehydrated (have lost too much body fluid). Dehydration can occur if you are sick with severe vomiting, diarrhea, or fever, or if you drink a lot less fluid than normal.
 - o plan to have surgery
 - o are going to get an injection of dye or contrast agent for an x-ray procedure. See "What is the most important information I should know about JENTADUETO?" and "Who should not take JENTADUETO?".
- When your body is under some types of stress, such as fever, trauma (such as a car accident), infection, or surgery, the amount of diabetes medicine that you need may change. Tell your doctor right away if you have any of these conditions and follow your doctor's instructions.
- Check your blood sugar as your doctor tells you to.
- Stay on your prescribed diet and exercise program while taking JENTADUETO.
- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.
- Your doctor will do blood tests to check how well your kidneys are working before and during your treatment with JENTADUETO.

What are the possible side effects of JENTADUETO tablets? JENTADUETO may cause serious side effects, including:

- See "What is the most important information I should know about JENTADUETO?"
 - low blood sugar (hypoglycemia). If you take JENTADUETO with another
 medication that can cause low blood sugar, such as sulfonylurea or insulin, your risk of
 getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin
 may need to be lowered while you take JENTADUETO. Signs and symptoms of low
 blood sugar may include:

headache	• irritability
• hunger	• drowsiness
fast heart beat	 weakness
• sweating	• dizziness
feeling jittery	• confusion

The most common side effects of JENTADUETO include:

- stuffy or runny nose and sore throat
- diarrhea

These are not all the possible side effects of JENTADUETO. For more information, ask your doctor or pharmacist.

Tell your doctor if you have any side effects that bother you or that do not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store JENTADUETO tablets?

- Store JENTADUETO between 68°F and 77°F (20°C and 25°C).
- Keep tablets dry.

Keep JENTADUETO and all medicines out of the reach of children.

General information about the safe and effective use of JENTADUETO

Medicines are sometimes prescribed for purposes other than those listed in Medication Guides. Do not use JENTADUETO for a condition for which it was not prescribed. Do not give JENTADUETO to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about JENTADUETO. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about JENTADUETO that is written for health professionals.

For more information, go to www.jentadueto.com or call Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257, or (TTY) 1-800-459-9906.

What are the ingredients in JENTADUETO?

Active Ingredients: linagliptin and metformin hydrochloride

Inactive Ingredients: arginine, corn starch, copovidone, colloidal silicon dioxide, magnesium stearate, titanium dioxide, propylene glycol, hypromellose, talc.

- 2.5 mg/500 mg and 2.5 mg/850 mg tablets also contain yellow ferric oxide.
- 2.5 mg/850 mg and 2.5 mg/1000 mg tablets also contain red ferric oxide.

What is type 2 diabetes?

Type 2 diabetes is a condition in which your body does not make enough insulin, and/or the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems.

The main goal of treating diabetes is to lower your blood sugar to a normal level. High blood sugar can be lowered by diet and exercise, and by certain medicines when necessary.

Talk to your doctor about how to prevent, recognize, and take care of low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), and other problems you have because of your diabetes.

This Medication Guide has been approved by the U. S. Food and Drug Administration.

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